

East Building, PHH-30 1200 New Jersey Avenue S.E. Washington, D.C. 20590

Pipeline and Hazardous Materials Safety Administration

DOT-SP 14969

(FOR RENEWAL, SEE 49 CFR § 107.109)

EXPIRATION DATE: July 31, 2012

1. GRANTEE: Pace Air Freight, Inc. Plainfield, IN

2. PURPOSE AND LIMITATION:

- a. This special permit authorizes the one-way transportation in commerce of certain Category A infectious substances in special packagings in a dedicated truck by highway via pre-determined routes. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
- b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
- c. Unless otherwise stated herein, this special permit consists of the special permit authorization letter issued to the grantee together with this document.
- c. No party status will be granted to this special permit.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196(a) & (b), & 49 CFR § 173.199 in that packaging requirements are waived; and 178.609 in that test requirements for packagings are waived.

- 5. BASIS: This special permit is based on the application of Pace Air Freight, Inc. dated June 25, 2010 submitted in accordance with \$ 107.105 and the public proceeding thereon.
- 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Infectious substances, affecting humans*	6.2	UN2814	N/A
<pre>Infectious substances, affecting animals*</pre>	6.2	UN2900	N/A

^{*}Infectious substances for which effective treatments and preventive measures are not usually available are not allowed under this special permit.

7. SAFETY CONTROL MEASURES:

a. PACKAGING -

(1) Infectious substances, as listed in Paragraph 6, must be packed as follows: The substances, contained in sealed cryo-vials (primary receptacles), must be packaged in individual cryoval boxes. The volume of the substance in each vial must be between 2 mL and 12 mL. Not more than 100 vials may be packed in a cryoval box. Not more than 450 boxes must be placed on racks in a freezer. Hermetically-sealed vials (primary receptacles), placed on vial racks, must be wrapped in a plastic bag prior to placing the vial racks on racks in an electrically- powered specially designed freezer. Each box is secured with filler to prevent movement and to absorb the material in case of breakage. A sufficient amount of absorbent material must be placed in each freezer to absorb the entire contents of all primary receptacles in case of breakage or leakage and to prevent the contents from shifting during transport. The freezer serves as the outer packaging.

- (2) Not more than 45,000 vials may be packed in a freezer.
- (2) All freezers are constructed of stainless steel, maintained at -20 °C to -80 °C and are double-walled.
- (3) Boxes and racks must be tightly secured within the freezer to prevent the contents from shifting.
- (4) All freezer doors and lids must be securely closed and wrapped to prevent opening during transportation.
- (5) The infectious substances in the freezers must be kept frozen at all times within the operating temperature range of $-20~^{\circ}\text{C}$ to $-80~^{\circ}\text{C}$ maintained by electric power.
- (6) All freezers must be secured against movement in the transport vehicle.

b. OPERATIONAL CONTROLS -

- (1) This special permit authorizes the one-way transport of packages containing infectious substances from the existing bio-storage facility of BioStorage Technologies to relocating location at 2910 Fortune Circle West, Suite E, Indianapolis, Indiana 46241.
- (2) For one-way shipment from any other location to destination, pre-determined routes and alternate back-up routes in the event of an emergency pre-determined by Pace Air Freight must be carried on the transport vehicle.
- (3) Dry ice sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time must be carried on the transport vehicle as a back-up should the generators on the truck fail.
- (4) Not more than one transport vehicle may be operated at all times.
- (5) The transport vehicle will have a trailer with a back-up generator and freezer to ensure freezer operation should any freezer fail.

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- (6) Not more than eight freezers may be in a transport vehicle not to exceed 360,000 vials in a transport vehicle.
- (7) An itemized list of contents must be securely attached to the outside of each freezer.
- (8) Emergency equipment necessary to mitigate a spill must accompany each transport vehicle.
- (9) The transport vehicle must be driven by a trained driver.
- (10) No other hazardous material will be carried onboard the truck.

8. SPECIAL PROVISIONS:

- a. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this special permit and the HMR.
- b. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.
- 10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each cargo vessel, aircraft, or motor vehicle used to transport packages covered by this special permit. The shipper must furnish a copy of this special permit to the air carrier before or at the time the shipment is tendered.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 <u>et seq</u>:
 - o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by \$107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:

Duck By

for Dr. Magdy El-Sibaie

Associate Administrator for Hazardous Materials Safety

August 16, 2010

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: LAVALLE/S Hwang